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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/510,506	01/05/2005	Heinz Von Der Kammer	P67785US1	6896

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JACOBSON HOLMAN PLLC
400 SEVENTH STREET N.W.
SUITE 600
WASHINGTON, DC 20004

EXAMINER

SHEN, WU CHENG WINSTON

ART UNIT	PAPER NUMBER
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1632

DATE MAILED: 09/19/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/510,506

Applicant(s)

VON DER KAMMER ET AL.

Examiner

Wu-Cheng Winston Shen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-21 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

The examiner prosecuting this case has changed. All inquiries directed to the application should be directed to examiner W. C. Winston Shen

Election/Restrictions

1. In response to the restriction Requirement mailed on June 13, 2006, applicants elected to prosecute invention of Group VI, claims 13-18 and 20 (amended version, total 21 claims, filed on 10/7/2004).

Election was treated as an election **without** traverse in the reply filed on June 28, 2006 because the reply does not distinctly and specifically point out supposed errors in the Restriction Requirement.

However, upon further consideration, further restriction of the claims 13-18 and 20 is required as follows. Additionally, restriction of claims 11-12 (Group V) has been re-considered. A new set of claims 11-18 and 20 is set forth below.

2. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

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Group V has been modified as follows: Claim 11, 12 and 13, drawn to a method of making a transgenic non-human animal and a method of using of a transgenic non-human animal, comprising a non-native gene sequence coding for a vault protein, the minor vault protein ADPRTL1, or a fragment, or a derivative, or a variant thereof, wherein ADPRTL1 is the minor vault protein of SEQ ID NO: 2.

Group VI has been modified as follows: Claim 14 (in part), drawn to an assay for screening for a modulator of neurodegenerative disease, in particular Alzheimer's disease, or related diseases or disorders of a substance of a gene coding for a vault protein, the minor vault protein ADPRTL1 or a transcription product or variant of the transcription product of a gene coding for a vault protein, the minor vault protein ADPRTL1, a *nucleic acid* based assay.

Claims 14 (in part) – 18, and 20 have been put in new Groups VIII-XIII as follows:

VIII. Claims 14 (in part), drawn to an assay for screening or testing for a modulator or a compound of neurodegenerative disease, in particular Alzheimer's disease, or related diseases or disorders of a substance of a translation product or a fragment or derivative of the translation product of a gene coding for a vault protein, the minor vault protein ADPRTL1, or a compound for inhibition of binding between a ligand and ADPRTL1 vault protein, a *protein* based assay.

IX. Claim 15-16 (in part), drawn to a method of screening for a modulator of neurodegenerative diseases, in particular Alzheimer's disease, or related diseases or disorders of a substance of a *ADPRTL1* gene coding for a vault protein, the minor vault protein ADPRTL1 or a transcription product or variant of the transcription product of a gene coding for a vault protein,

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the minor vault protein ADPRTL1, wherein the said method comprising a test compound to a test animal, a *nucleic acid* based method of screening.

X. Claim 15-16 (in part), drawn to a method of screening for a modulator of neurodegenerative diseases, in particular Alzheimer's disease, or related diseases or disorders of a substance of a translation product or a fragment or derivative of the translation product of a *ADPRTL1* gene coding for a vault protein, the minor vault protein ADPRTL1, wherein the said method comprising administering a test compound to a test animal, a *protein* based method of screening.

XI. Claim 17-18, drawn to an assay for testing a compound, preferably for screening a plurality of compound for inhibition of binding between a ligand and vault protein, the major vault protein, and the binding of said compound to a vault protein ADPRTL1, or a fragment, or derivative thereof.

XII. Claim 20 (in part), drawn to a method of using a protein molecule, said protein molecule being a translation product of the gene coding for a vault protein, the minor vault protein ADPRTL1, SEQ No: 2, or a fragment, or derivative thereof, as a diagnostic target for *detecting* or a *screening* for reagents preventing a neurodegenerative disease, preferably Alzheimer's disease.

XIII. Claim 20 (in part), drawn to a method of using a protein molecule, said protein molecule being a translation product of the gene coding for a vault protein, the minor vault protein ADPRTL1, SEQ No: 2, or a fragment, or derivative thereof, as a target for *preventing* or *treating* a neurodegenerative disease, preferably Alzheimer's disease.

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3. The inventions listed as Groups V, VI and VIII-XIII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Applicant's claims encompass multiple inventions and do not have a special technical feature which link the inventions one to the other, and lack unity of invention. The common technical feature in all groups the minor vault protein ADPRTL1. However, this common technical feature cannot be a special technical feature under PCT Rule 13.2 because the feature is shown in the prior art. Still et al published the identification of a novel gene *ADPRTL1* (Still et al. Identification of a novel gene (*ADPRTL1*) encoding a potential Poly(ADP-ribosyl) transferase protein. *Genomics*. 62(3): 533-6, 1999). The reference further teaches the alignment of amino acids of five Adprt proteins and the catalytic domain of Adprt1.

Inventions of the Groups V, VI, and VIII-XIII are patentably distinct each from the other. Inventions are patentably distinct if it can be shown that they are not disclosed as capably of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06).

Group V is directed to a method of making a transgenic non-human animal and a method of using of a transgenic non-human animal, comprising a non-native gene sequence coding for a vault protein, the minor vault protein ADPRTL1, or a fragment, or a derivative, or a variant thereof, wherein ADPRTL1 is the minor vault protein of SEQ ID NO: 2.

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Group VI is directed drawn to an assay for screening for a modulator of neurodegenerative disease, in particular Alzheimer's disease, or related diseases or disorders of a substance of a gene coding for a vault protein, the minor vault protein ADPRTL1 or a transcription product or variant of the transcription product of a gene coding for a vault protein, the minor vault protein ADPRTL1, a *nucleic acid* based assay whereas Group VIII is directed to an assay for screening or testing for a modulator or a compound of neurodegenerative disease, in particular Alzheimer's disease, or related diseases or disorders of a substance of a translation product or a fragment or derivative of the translation product of a gene coding for a vault protein, the minor vault protein Adprt11, or a compound for inhibition of binding between a ligand and Adprt11 vault protein, a *protein* based assay.

Group IX is directed to a method of screening for a modulator of neurodegenerative diseases, in particular Alzheimer's disease, or related diseases or disorders of a substance of a *ADPRTL1* gene coding for a vault protein, the minor vault protein ADPRTL1 or a transcription product or variant of the transcription product of a gene coding for a vault protein, the minor vault protein Adprt11, wherein the said method comprising a test compound to a test animal, a *nucleic acid* based method of screening whereas Group X is directed to a method of screening for a modulator of neurodegenerative diseases, in particular Alzheimer's disease, or related diseases or disorders of a substance of a translation product or a fragment or derivative of the translation product of a *ADPRTL1* gene coding for a vault protein, the minor vault protein ADPRTL1, wherein the said method comprising administering a test compound to a test animal, a *protein* based method of screening.

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Group XI is directed to an assay for testing a compound, preferably for screening a plurality of compound for inhibition of binding between a ligand and vault protein, the major vault protein, and the binding of said compound to a vault protein ADPRTL1, or a fragment, or derivative thereof.

Group XII is directed to a method of using a protein molecule, said protein molecule being a translation product of the gene coding for a vault protein, the minor vault protein ADPRT1, SEQ No: 2, or a fragment, or derivative thereof, as a diagnostic target for *detecting* or a *screening* for reagents preventing a neurodegenerative disease, preferably Alzheimer's disease whereas Group XIII is directed to a method of using a protein molecule, said protein molecule being a translation product of the gene coding for a vault protein, the minor vault protein ADPRT1, SEQ No: 2, or a fragment, or derivative thereof, as a target for *preventing* or *treating* a neurodegenerative disease, preferably Alzheimer's disease.

The search of the above listed Groups is distinct one from each other and not co-extensive and thereby presents search burdens on the examiner.

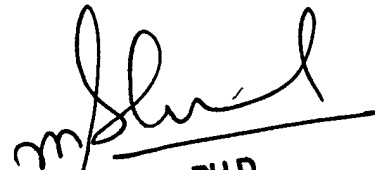
4. Because these inventions are independent or distinct for the reasons given above and the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.


5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the

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currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication from the examiner should be directed to Wu-Cheng Winston Shen whose telephone number is (571) 272-3157 and Fax number is 571-273-3157. The examiner can normally be reached on Monday through Friday from 8:00 AM to 4:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the supervisory patent examiner, Ram Shukla, can be reached on (571) 272-0735. The fax number for TC 1600 is (571) 273-8300. Any inquiry of a general nature, formal matters or relating to the status of this application or proceeding should be directed to Dianiece Jacobs whose telephone number is (571) 272-0532.


RAM R. SHUKLA, PH.D.
SUPERVISORY PATENT EXAMINER


Wu-Cheng Winston Shen, Ph. D.
Patent Examiner
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